

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

IN RE: Bair Hugger Forced Air Warming
Products Liability Litigation

MDL No. 2666 (JNE/FLN)

This Document Relates to
ALL ACTIONS

**DEFENDANTS' MEMORANDUM IN OPPOSITION
TO PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY
OF ALEXANDER A. HANNENBERG, M.D.**

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INTRODUCTION

This Court should deny Plaintiffs' motion to exclude the expert opinion testimony of Alexander A. Hannenberg, M.D., a board-certified anesthesiologist, who has been offered by Defendants as a rebuttal expert on the issue of general causation. Dr. Hannenberg's opinion that the Bair Hugger system is safe and effective is well grounded in extensive professional knowledge and clinical experience using the Bair Hugger system, as well as his review of the relevant scientific literature.

Anesthesiologists use patient warming devices, such as the Bair Hugger system, to maintain a patient's body temperature during surgery. Anesthesiologists monitor patients' temperatures throughout a surgical procedure. Dr. Hannenberg is the only anesthesiologist designated as an expert by either side in this litigation, and therefore his opinions will be of particular value to the trier of fact. Those opinions are: (1) the Bair Hugger system is safe and effective at maintaining normothermia (normal body temperature) and preventing hypothermia, and therefore reduces the risk of surgical site infections; (2) there is a lack of scientifically credible evidence that the Bair Hugger system causes surgical site infections; and (3) labeling for the Bair Hugger system does not require a warning of a risk of infection since no credible scientific evidence establishes that the Bair Hugger system causes infections. DX1, Hannenberg Rpt. at 2-3, 6.¹ Dr. Hannenberg squarely rebuts the opinions of Plaintiffs' experts.

¹ All citations to "DX" in this memorandum are to the exhibits to the Declaration of Deborah E. Lewis in Opposition to Plaintiffs' Motion to Exclude the Testimony of Defendants' Expert Alexander A. Hannenberg, M.D, filed contemporaneously with this memorandum.

Dr. Hannenberg's methodology was reliable. Dr. Hannenberg based his expert opinions on more than 20 years of using the Bair Hugger system in his clinical practice; his knowledge, education and training on the benefits of normothermia and risks of hypothermia; the data from his hospital reflecting low infection rates; and review of the vast number of peer-reviewed scientific studies on the benefits of patient warming systems and normothermia. His opinions are corroborated by independent and highly respected groups in the relevant science and medical fields who also reject Plaintiffs' experts' conclusions. DX1 at 2-3. Dr. Hannenberg's literature review included the same studies on which Plaintiffs' experts rely, all of which disclaim any finding that the Bair Hugger system causes surgical site infections. DX1 at 3-5.

In sum, Dr. Hannenberg has a strong, scientifically valid and reliable foundation for his opinions rebutting Plaintiffs' experts, and easily satisfies the standard for admissibility under Fed. R. Evid. 702 and Minn. R. Evid. 702. Plaintiffs' motion to exclude his opinions and testimony should be denied.

ARGUMENT

I. DR. HANNENBERG'S OPINION THAT THE BAIR HUGGER SYSTEM IS SAFE AND EFFECTIVE IS BASED ON HIS EXTENSIVE PROFESSIONAL CLINICAL EXPERIENCE AND REVIEW OF THE SCIENTIFIC LITERATURE.

Plaintiffs argue that Dr. Hannenberg did not adhere to a valid scientific methodology in reaching his opinions. Pl. Mem. at 8. They are wrong.

Dr. Hannenberg employed a sound and valid scientific methodology to reach his conclusions, and his conclusions are reliable. His expert report makes clear that he reaches

his opinions that the Bair Hugger system is safe and effective by drawing on his extensive professional clinical experience using the Bair Hugger system, his review of the published scientific literature, data from his hospital on low infection rates, and those conclusions and endorsements reached by independent and well-respected authorities in the relevant science and medical disciplines. This is a well-recognized and scientifically valid methodology for reaching opinions in products liability litigation. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999) (an expert's opinion may be based on "professional studies or personal experience").

Moreover, Plaintiffs ignore the fact that Dr. Hannenberg is a rebuttal expert. That means his primary purpose in this litigation is to critique the theories and experts of Plaintiffs, who have the burden of proof. As this Court has recognized, "[i]t is the proper role of rebuttal experts to critique plaintiffs' expert's methodologies and point out potential flaws in the plaintiff's expert's reports." *Aviva Sports, Inc. v. Fingerhut Direct Mktg., Inc.*, 829 F. Supp. 2d 802, 834 (D. Minn. 2011), *quoting Marmo v. Tyson Fresh Meats, Inc.*, 457 F. 3d 748, 759 (8th Cir. 2006). As such, Dr. Hannenberg's opinions are still admissible even if he offers pure critique, rather than independent theories and conclusions. *Id.*, *quoting In re Cessna 208 Series Aircraft Prods. Liab. Litig.*, MDL No. 1721, 2009 WL 1649773, at *1 (D. Kan. June 9, 2009) (a rebuttal expert who critiques another expert's theories or conclusions need not offer his own independent theories or conclusions).

A. Dr. Hannenberg Based His Opinions, First, on His More Than 20 Years of Using the Bair Hugger System in Major Orthopedic Surgeries.

In challenging the admissibility of Dr. Hannenberg's opinions, Plaintiffs argue, strangely, that Dr. Hannenberg's opinions are based only on a review of literature and not on his professional experience. Pl. Mem. at 5-6. Even if that were a valid basis to attack an expert (and it is not), a cursory review of Dr. Hannenberg's expert report makes clear that he draws on *both* his professional clinical experience in anesthesiology and his review of the scientific literature.

It is well established that an expert's opinions can be based on personal experience. *Kumho Tire*, 526 U.S. at 152. Dr. Hannenberg has over 30 years of experience practicing anesthesia and administering general anesthesia in major orthopedic surgeries. DX1 at 2. Dr. Hannenberg describes how for over 20 years he has used the Bair Hugger system in virtually every hip or knee replacement in more than 400 total joint replacement operations. His practice of employing of the Bair Hugger system is based on his clinical experience using the Bair Hugger system; his knowledge of and review of peer-reviewed published scientific literature showing the efficacy of forced air warming, including the Bair Hugger system; his knowledge of other anesthesiologists' (peer group) practice to use forced air warming; and independent and highly respected groups in the relevant science and medical disciplines who endorse the use of forced air warming. DX1 at 2-3.

Dr. Hannenberg's relevant professional experience goes beyond his practice at Newton Wellesley Hospital. He has held several positions in the American Society of Anesthesiologists and was responsible for the Society's work on professional standards

and patient safety. He has served as Chair of the American Medical Association's Physician Consortium for Performance Improvement, working on developing performance measures in anesthesiology. One of those measures developed by the AMA Consortium addressed perioperative temperature management, which was subsequently adopted by Medicare's Physician Quality Reporting System and was endorsed by the National Quality Forum. DX1 at 1. As related in his report, all this clinical and professional association experience contributes to and supports Dr. Hannenberg's opinions on the safety and efficacy of the Bair Hugger system. DX1 at 2-3.

Through his extensive clinical use of the Bair Hugger system and knowledge of the benefits derived from preventing hypothermia, including a reduction in surgical site infections, Dr. Hannenberg has "found forced air warming to be safe, easy to use, and effective at maintaining patients' normal temperatures." DX1 at 2. Moreover, his use of the Bair Hugger system at Newton Wellesley Hospital "has been part of [his] strategy to reduce the likelihood of surgical site infection." *Id.* Dr. Hannenberg provides data from Newton-Wellesley Hospital – which has exclusively used the Bair Hugger system – showing the hospital's recent data on infection rates as low as 0.6%, which is approximately half the prevailing national infection rate.² *Id.* Newton Wellesley's data on

² Plaintiffs cite a CMS Hospital Compare report showing that *complications* for hip/knee replacement at Newton-Wellesley Hospital are no different than the national rate. Pl. Mem. at 19. The CMS report does not compare *infection* rates, and therefore does not in any way undermine Dr. Hannenberg's statements about the low infection rate at Newton-Wellesley. Complications are a far broader category than infections (e.g. takes into account how sick patients were when they were hospitalized), and the CMS report does not define or further explain the meaning of complications.

its low infection rates also supports Dr. Hannenberg's conclusions on the safety of the Bair Hugger system and the benefits of maintaining normal body temperature with patient warming therapy, including reducing the risk of surgical site infections. *Id.* Plaintiffs assert that Dr. Hannenberg has failed to consider other possible factors for the low infection rate in his practice, but he makes clear that he did. Dr. Hannenberg also clearly explains in his report that the anesthesiologist's treatment of hypothermia, avoidance of hyperglycemia and timely administration of prophylactic antibiotics all impact and help mitigate the frequency of surgical infections.³ DX1 at 3.

B. Dr. Hannenberg Based His Opinions, Second, on His Review of the Scientific Literature.

Medical experts may rely on published literature to support expert opinions and need not conduct their own studies to offer an opinion. *Kumho*, 526 U.S. at 150; *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 412 (S.D.N.Y. 2016) (noting, in denying *Daubert* challenges to defendants' medical experts in a medical device MDL, that a review of other studies and scientific literature can be enough to qualify experts to testify and to make that proposed testimony reliable). Dr. Hannenberg relied on a review of scientific literature, and (as he notes) his opinions are further corroborated by multiple

³ Plaintiffs' contention that Dr. Hannenberg does not personally follow up with patients after surgery and does not know whether his patients develop a joint infection is not relevant and misses the point. Pl. Mem. at 7, 14. Anesthesiologists do not typically follow up with patients after they leave the recovery room. Dr. Hannenberg also makes clear that he relies on published scientific literature to support his conclusion that prevention of hypothermia reduces the risk of surgical site infections. DX1 at 2-3.

independent and highly respected science and medical groups worldwide who have also reviewed the scientific literature.⁴

First, Dr. Hannenberg's conclusion that the Bair Hugger system maintains normothermia, prevents hypothermia and reduces the risk of surgical infections is well supported by the scientific literature. For example, he has identified and listed several scientific studies that support the efficacy of forced air warming, including the Bair Hugger system,⁵ and the landmark peer-reviewed, randomized controlled clinical study – the Kurz⁶ study – demonstrating that prevention of hypothermia reduced the risk of surgical site infection and the associated reduction in wound infection rate (and which notably used the Bair Hugger system to achieve normothermia in the patients). DX1 at 2.

Second, Dr. Hannenberg relies on the Avidan⁷ study, which showed that air emitted from the Bair Hugger *blanket* – the way the Bair Hugger system is intended to be used –

⁴ DX1 at 2: ERICI Institute, AMA Physician Consortium for Performance Improvement, US Centers for Medicare & Medicaid Services, American Society of Perianesthesia Nurses, the UK National Institute for Clinical Excellence (NICE). *See also* DX1 at 27, September 6, 2017 Supplemental Expert Report of Alexander A. Hannenberg, M.D.

⁵ Dr. Hannenberg cites four studies: Hynson JM, Sessler DI. “Intraoperative warming therapies: a comparison of three devices,” 4 *J. Clin. Anesth.* 194 (1992); Giesbrecht GG, et al., “Comparison of forced-air patient warming systems for perioperative use,” 80 *Anesthesiology* 671 (1994); Berti M, et al., “Active warming, not passive heat retention, maintains normothermia during combined epidural-general anesthesia for hip and knee arthroplasty,” 9 *J. Clin. Anesth.* 482 (1997); and Kurz A, et al., “Forced-air warming maintains intraoperative normothermia better than circulating-water mattresses,” 77 *Anesth Analg.* 89 (1993).

⁶ Kurz A, et al., “Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization.” 334 *New England J. Med.* 1209 (1996).

⁷ Avidan M.S., et al., “Convection warmers – not just hot air.” 52(11) *Anesthesia* 1073

did not produce bacterial growth when cultured. DX1 at 4. He further relied on this study to rebut the opinions of two of Plaintiffs' experts, Drs. Stonnington and Jarvis, who speculate that inadequate air filtration in the Bair Hugger system increases the risk of surgical site infections. Dr. Hannenberg notes that Avidan's finding of negative cultures from the Bair Hugger blanket air flow contradicts Stonnington's and Jarvis' unsupported opinions. DX1 at 4. In other words, he finds no support for the argument that the Bair Hugger system filter (contained in the warming unit) is inadequate to prevent infections when the Bair Hugger system is used as intended with the blanket attached. No bacteria grew on culture plates placed below the Bair Hugger blanket. The actual clinical use of the Bair Hugger system is, of course, what matters in this litigation.⁸

Third, Dr. Hannenberg's conclusion that the scientific literature does not demonstrate that the Bair Hugger disrupts "laminar airflow" in a manner to increase infection risk is also well supported. Dr. Hannenberg cites a controlled and influential scientific study which included more than 99,000 operations and concluded that "OR ventilation with laminar airflow showed no benefit and was even associated with a significantly higher risk for severe SSI after hip prosthesis."⁹ He further notes that the emission of air from the Bair Hugger blanket is outside of the laminar flow environment,

(1997).

⁸ Dr. Hannenberg's expert report further reflects the many studies and literature he also considered in reaching his opinions in this litigation. DX1 at 8.

⁹ Brandt C, et al., "Operating room ventilation with laminar airflow shows no protective effect on the surgical site infection rate in orthopedic and abdominal surgery." 248 *Ann Surg.* 695 (2008).

making Plaintiffs’ theory – and the opinions of Drs. Stonnington and Jarvis – of laminar air flow interference irrelevant in actual clinical practice. DX1 at 4. That Dr. Hannenberg is not an expert in operating room airflow does not make it improper for him to reach a conclusion based on the scientific literature and his extensive experience in the operating room. As noted above, an expert can rely on published studies. *Kumho Tire*, 526 U.S. at 152 (an expert’s opinion may be based on “professional studies”); *In re Mirena IUD Prods. Liab. Litig.*, 169 F.Supp.3d at 412 (a review of other studies and scientific literature can be enough to qualify experts to testify and to make that proposed testimony reliable); *Ratliff v. Schiber Truck Co.*, 150 F.3d 949, 955 (8th Cir. 1998) (permitting accident reconstructionist to rely on police officer’s report because it was “of the type reasonably relied upon by accident reconstructionists in forming their opinions”).

Fourth, Dr. Hannenberg appropriately accounted for the McGovern study and the other studies on which Plaintiffs and their experts rely. Each of these studies expressly disclaims any finding of causation. Dr. Hannenberg’s conclusion that he is “not aware of a single credible scientific study causally linking the use of the Bair Hugger to an increased risk of surgical site infections” is therefore well supported by the literature. DX1 at 6.

Fifth, that Dr. Hannenberg did not review certain deposition testimony or certain other studies cited by Plaintiffs, and did not review internal corporate documents, does not render his methodology scientifically unsound. In fact, Plaintiffs fail to demonstrate that the various depositions, studies and internal documents they list in their memorandum are

all relevant¹⁰ and would have impacted Dr. Hannenberg's opinions. Pl. Mem. at 10-13. Plaintiffs also fail to cite any authority for their proposition that an expert must review nearly all depositions, studies and internal documents to constitute a scientific methodology. If the law required this, and it does not, then every single one of Plaintiffs' experts would be excluded on the same basis. What Dr. Hannenberg considered in reaching his opinions is more than sufficient to satisfy *Daubert* and Rule 702.

Finally, the fact that Dr. Hannenberg does not compare the safety of the Bair Hugger system to other patient warming devices does not support exclusion of his testimony. Pl. Mem. at 18. Plaintiffs' experts opine that the Bair Hugger system increases the risk of surgical site infections; Dr. Hannenberg rebuts that opinion based on his professional clinical experience and his review of the scientific literature, particularly those scientific studies showing a reduction in surgical site infections. A comparison to other patient warming devices is beyond the scope of his opinions.

Based on all of the above steps undertaken and a review of the scientific literature, Dr. Hannenberg's methodology and opinions are scientifically valid, reliable, and will assist the trier of fact.

¹⁰ For example, Plaintiffs list studies on particles – Stocks and Darouiche – that do not involve the Bair Hugger system.

C. Plaintiffs Consistently Misrepresent the Content of Dr. Hannenberg's Report and Deposition Testimony.

Something must be said about the numerous times Plaintiffs contend that documents say things they do not actually say,¹¹ and cite Dr. Hannenberg's deposition testimony for arguments not supported by the testimony cited. Two of Plaintiffs' most egregious misrepresentations are addressed here. First, Plaintiffs claim that Dr. Hannenberg "admits that he has no expertise in normothermia other than simply using a Bair Hugger to manage patient body temperatures," or that Dr. Hannenberg readily admits that both Dr. Kurz and Dr. Sessler are experts in the field, but "concedes he does not have their expertise." Pl. Mem. at 5-6. Dr. Hannenberg makes no such admission or concession. For the testimony Plaintiffs cite, DX2, Hannenberg Deposition at 27:20-29:22, Dr. Hannenberg simply answered questions whether he knew Drs. Kurz and Sessler, whether they had done more research on normothermia than he had, and whether he had done laboratory research, clinical studies or published on normothermia. It is nothing more than that.

Second, Plaintiffs' claim that Dr. Hannenberg "has no basis at all upon which to opine that the Bair Hugger is safe" comes from testimony taken out of context, and thus

¹¹ See fn. 2, *infra*. Plaintiffs also erroneously contend that Dr. Hannenberg "never discusses in his report any methodology" to render his opinions. Pl. Mem. at 8. To the contrary, Dr. Hannenberg's report identifies and explains in detail the materials he reviewed and considered, including published scientific studies and literature on normothermia and the benefits of normothermia; his personal clinical experience using the Bair Hugger system for over 20 years; his education, training, experience and knowledge of the literature; his review of a published scientific study questioning the benefit of laminar air flow; his review of studies, including McGovern, that expressly disclaim a causal nexus between Bair Hugger system use and surgical site infections; and his reliance on impartial and expert review of the scientific literature from independent and highly respected science and medical groups worldwide. DX1 at 2-8.

misrepresents Dr. Hannenberg's overall testimony on the safety of the Bair Hugger system. Pl. Mem. at 14. DX2 at 288:11-289:4. As an initial matter, Plaintiffs have not included all of the testimony in their citation. Furthermore, the full context of Plaintiffs' questioning begins earlier where Plaintiffs asked whether Dr. Hannenberg had performed studies on bacterial load and periprosthetic joint infections. DX2 at 286:25-287:4. Plaintiffs then asked whether Dr. Hannenberg's credentials would indicate that the Bair Hugger does not increase the *bacterial load* over the surgical site. DX2 at 287:22-288:4. The next question then shifts to whether Dr. Hannenberg's experience allowed him to determine whether the Bair Hugger has any effect on the *airflow* that could increase the bacterial load over the surgical site. DX2 at 288:11-15. The final question shifts again and asked whether Dr. Hannenberg had a *methodology* to offer the opinion that the Bair Hugger *does not increase the bacterial load* over the surgical site and is safe. DX2 at 288:20-289:2. Not only does Dr. Hannenberg not even offer an opinion on bacterial load over the surgical site (thus, his response of "correct" to the question asked was appropriate since the question asked was concerning a *methodology* on an opinion he has not offered), Plaintiffs take his response out of context as a veiled attempt to suggest that Dr. Hannenberg admits he has no basis for his opinion that the Bair Hugger system is safe. As discussed above, Dr. Hannenberg has been very clear on his opinion on the safety of the Bair Hugger system and the bases of his opinion.

D. Dr. Hannenberg's Labeling Opinion Is Also Reliable.

Dr. Hannenberg's opinion that the Bair Hugger system's labeling is appropriate is likewise supported by his extensive professional clinical experience and review of the

scientific literature. DX1 at 6. Anesthesiologists, whose clinical practice incorporates administration of patient temperature management by use of patient warming therapy devices, are the healthcare practitioners to whom a patient warming device manufacturer's labeling and warnings are addressed. As such, as the only anesthesiologist disclosed by either side, Dr. Hannenberg is uniquely qualified to opine on whether the Bair Hugger warning and labeling are reasonable. Warnings of a risk of infection is not necessary because there is no credible evidence of a risk. *Id.* The FDA's recent Letter to Health Care Providers dated August 30, 2017, which notes its recommendation to continue use of forced air warming devices, further corroborates and shows the reliability of Dr. Hannenberg's opinion that a warning of a risk of infection is unwarranted. DX1 at 27.

II. DR. HANNENBERG'S OPINIONS ARE GENERALLY ACCEPTED AS PROVIDED BY MINN. R. EVID. 702.

Minn. R. Evid. 702 states that a qualified expert's opinions and testimony are admissible if they have both: (1) foundational reliability, and (2) general acceptance in the relevant scientific community. *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000). *See also McDonough v. Allina Health Sys.*, 685 N.W.2d 688, 696 (Minn. App. 2004) (affirming the district court's determination that plaintiff's expert's general causation theory is not generally accepted). As detailed above, Dr. Hannenberg's opinions are appropriately based on his extensive professional knowledge and clinical experience, and his review of the scientific literature. Unlike Plaintiffs' experts' opinions, his conclusions are generally accepted in the scientific and medical communities. As such, Dr. Hannenberg's opinions are admissible in the Minnesota state cases.

CONCLUSION

Dr. Hannenberg's expert testimony and opinions are admissible under Fed. R. Evid. 702 and Minn. R. Evid. 702. His testimony rebuts Plaintiffs' experts on key issues concerning the safety and efficacy of the Bair Hugger system. His opinions will assist the trier of fact in understanding patient warming therapy, use of the Bair Hugger system, the benefits of normothermia and the prevention of hypothermia during general anesthesia, and the evidence showing that the prevention of hypothermia reduces the risk of surgical site infections.

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Respectfully submitted,

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